DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

D1141B
PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

January 29, 1997

97-PHI-12

Certified Mail
Return Receipt Requested

GEN. SPEC.
RELEASE
F# _____ DATE _____
Reviewed by: Wm. M. Foote

Ken Scarlino, President
Valley Home Medical Equipment, Inc.
1300 Seventh Avenue
Beaver Falls, PA 15010

Dear Mr. Scarlino:

On January 13-14, 1997, Investigator Cynthia Rakestraw of the US Food and Drug Administration conducted an inspection of your medical oxygen transfilling operation located in Beaver Falls, PA. At the conclusion of the inspection, she presented you with an FDA Form 483, List of Inspectional Observations. This form lists serious deviations from the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals as outlined in Title 21 Code of Federal Regulations (21CFR) part 211. Consequently, your product, oxygen, USP, is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the methods used in, or the facility used for their manufacture do not conform to CGMP regulations as follows:

1. You have no written procedures for any operation relating to the prefill testing, filling, postfill testing, labeling of cylinders, and maintenance of equipment for E size cylinders by the cascade method used at your facility. These procedures must be on hand for reference by the person performing the filling. [21 CFR 211.100]

2. You are filling E size cylinders from a bank of H cylinders without testing the filled cylinders for both identity and strength prior to release. None of the cylinders filled are assayed. [21 CFR 211.165(a)]

3. You have failed to establish batch and production control records for each batch of drug produced, including documentation that each step in the manufacture, packing or holding was accomplished. Also, no records have been reviewed and countersigned by a second person. [21 CFR 211.188(b)]

4. You have failed to perform adequate prefill operations on each

CFN: 2523836
bcc: W/L File, EF, HFR-MA1, HFR-MA100, HFR-230, HFD-300, HFI-35 (redacted), W/L Book, HFR-MA1515, HFA-224, Distr. by maz

high pressure cylinder prior to filling in that there is no record of prefill testing. [21 CFR 211.84(d)(3)]

This is not intended to be a comprehensive listing of the deficiencies discovered at your firm. It is your responsibility to assure that your company's operations are in compliance with the Act and the associated implementing regulations. For your reference, enclosed is a copy of the paper, "Fresh Air", which discusses the regulations for medical gas repacking operations.

We understand that you stated to Investigator Rakestraw that your firm would cease refilling medical oxygen cylinder effective January 14, 1997. We request that you confirm this action, in writing, within fifteen (15) working of your receipt of this letter. Please be advised that continued operation, without corrective action, may subject your products to further regulatory action. These actions include seizure and/or injunction.

Your reply should be sent to the attention of William W. Knipe, Compliance Officer, at the address noted above.

Sincerely,

Diana Kolaitis
District Director
Philadelphia District

cc: Pennsylvania State Dept of Health
Health and Welfare Building
7th and Forster Streets
P.O. Box 90
Harrisburg, PA 17120
Attn: Division of Primary Care and Home Health Service
Robert E. Bastian, Director